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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/474,388	06/07/95	SPRINGER T	[illegible]

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EXAMINER	
CUNNINGHAM, T	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 11/23/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/474,388	Applicant(s) Springer et al.
	Examiner Thomas Cunningham	Group Art Unit 1644

☒ Responsive to communication(s) filed on *Sep 8, 1998*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *71-73, 75-83, and 87-98* is/are pending in the application.

Of the above, claim(s) *87-98* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *71-73 and 75-83* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). The amendment filed July 6, 1998 has been entered.

2. (Moot) The prior rejection of claims 75-78 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as they recited the term "about" is moot in view of cancellation of this term.

3. Claim 79 is rejected under 35 U.S.C. 112, fourth paragraph as failing to further limit the claimed subject matter of independent claim 71. The ICAM-1 products of claim 1 would inherently have the same amino acid sequence as that of Fig. 8 as claimed in claim 79. Therefore, claim 79 does not further limit the subject matter of claim 71.

4. Claim 73 is rejected under 35 U.S.C. 112, fourth paragraph as failing to further limit the claimed subject matter of independent claim 72. The term "specifically bind" does not further limit the term used in claim 72 "bind".

5. Claim 71 is rejected under 35 U.S.C. 112, first paragraph as failing to describe so as to enable ICAM-1 having amino acid sequences other than the sequence of Fig. 8. There is no description of allelic variants, or mammalian homologs of ICAM-1 sequences, and it would have been unpredictable whether such variants exist. Thus, one with skill in the art would not have had a reasonable expectation of being able to make and use variants of ICAM-1 other than those having the sequence of Fig. 8.

6. Claims 71-73, 74-78 and 80-83 are rejected under 35 U.S.C. 112, first paragraph to the extent that they embrace ICAM-1 products that do not have the sequence of Fig. 8. It would be unpredictable what functional properties ICAM-1 products with variant sequences would have as substitution or deletion of even a single amino acid residue in an active site would be expected to alter the functional immunological or binding properties of such an ICAM-1 variant, see Smilek et al., PNAS 88:9633-9637, A single amino acid change in a myelin basic protein peptide confers the capacity to prevent rather than induce experimental autoimmune encephalomyelitis", (November, 1991). See abstract: Thus, substitution of a single amino acid in a myelin basic protein peptide confers the capacity to prevent rather than

induce EAE, even after peptide-specific encephalitogenic clones have been activated.

7. Claims 71-73 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Tomassini, thesis 8624033 (1986) or Tomassini et al., J. Virol. 58:290-295 (1986). These claims are directed to purified or isolated ICAM-1 preparations capable of binding to LFA-1, Mac-1 or p150,95. Page 58 of the cited document teach 400-fold immunoaffinity purified 90 kDa HRRP (ICAM-1). The cited document is silent as to whether the 90 kDa HRRP product (ICAM-1) binds to a member of the LFA-1 family, but would inherently have this property as it would comprise the same binding site residues as the ICAM-1 products encompassed by the instant claim language.

8. Claims 71-73 and 75-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomassini, thesis 8624033 (1986) or Tomassini et al., J. Virol. 58:290-295 (1986). These claims encompass forms of ICAM-1 produced in different human tissues or by different human cell lines, viz. claim 75 (spleen), claim 76 (JY cells), claims 77 (myelomonocytic cell line), and claim 78 (fibroblast).

The two cited references teach HRRP (ICAM-1) produced by HeLa cells. They do not teach HRRP (ICAM-1) produced in other cells.

Tomassini et al., page 295, first column, last paragraph indicates that the HRV receptor is ubiquitous in the human body, and thus one with ordinary skill in the art at the time of invention would have had a reasonable expectation of isolating HRRP (ICAM-1) from any tissue in the human body using the methods taught by the cited references for the purpose of studying of modulating the attachment of HRV to human tissues.

9. Claims 80 and 81 are rejected under 35 U.S.C. 102(b) as being Tomassini, thesis 8624033 (1986) or Tomassini et al., J. Virol. 58:290-295 (1986). The claims are directed to lipid membranes comprising isolated or purified ICAM-1. The cited references teach HeLa cell membrane preparations (see pages 20-21 of the dissertation) that bind to anti-HRRP (ICAM-1) antibody (see pages 40-41 of the dissertation). Page 58 teach 400-fold immunoaffinity purified 90 kDa HRRP (ICAM-1). It is unclear whether the instant claim language excludes ICAM-1 in eukaryotic cell membranes or ICAM-1 expressed recombinantly in prokaryotic or eukaryotic host cells. The cited reference also teaches purified HRRP (ICAM-1) that would be expected to be associated with lipid membranes in detergents. Accordingly, the claim

language has been interpreted broadly as encompassing the prior art cells that comprise ICAM-1.

10. (Withdrawn) The prior rejection of claims 71-79 and 86 rejected under 35 U.S.C. 102(a) over Dustin et al., J. Immunology 137:245 (July 1, 1986) is withdrawn in view of the declaration under 37 C.F.R. 1.132 provided.

11. (Withdrawn) The prior rejection of claims 71-79 under 35 U.S.C. 102(e) as being anticipated by Greve, U.S. patent 5,589,453 (priority to 9/1/88) is withdrawn in view of the amendment of the claim language and Applicant's arguments that priority for binding to LFA-1, Mac-1 or p150,95 can be found inter alia at pages 11-13 of 07/045,963. This application has been reviewed and provides descriptive support for claims to ICAM-1 binding the LFA-1 family of molecules. This family includes LFA-1, MAC-1 and p150,95. The filing date of 07/045,963 is prior to the effective filing date of the cited patent and thus the patent to Greve is not prior art to the ICAM-1 molecules described by 07/045,963.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas M. Cunningham, Ph.D, J.D. whose telephone number is (703) 308-3968.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

TC

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